

#313
8-20-98
RP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of :
Robert GARFIELD et al. : Group Art Unit:
Serial No.: Unassigned : Examiner:
(DIV of 08/092,426) ngr
Filed: HEREWITH :
For: **TREATMENT OF PREECLAMPSIA, TOXEMIA AND PRETERM LABOR
WITH COMBINATION OF PROGESTATIONAL AGENT AND A NITRIC
OXIDE SYNTHASE SUBSTRATE AND/OR DONOR**

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination and calculation of the claim fees, please amend the specification of the above-identified application as follows:

In the Claims:

Please amend claims 1-3, 14 and 18 as follows:

1. (Amended.) A method of treating at least one of preeclampsia, [and] accompanied or unaccompanied by preterm labor in a pregnant female mammal, [which comprises] or dysmenorrhea, functional uterine bleeding or hemorrhaging in a non-pregnant female mammal, comprising administering to [the afflicted] a pregnant female in need of said treatment an effective amount of a pharmaceutical composition of claim 14

[(a) an amount of a progestin bioequivalent to 50-300 mg. of injected progesterone and
(b) an amount of nitric oxide synthase substrate, an amount of a nitric oxide donor or both effective to raise the blood level of circulating L-arginine to at least about 1 mmole above the normally 2 to 3 mmolar circulating levels,
optionally, in further combination with one or more of with one or more of agents selected from the group consisting of a cyclooxygenase inhibitor, a PGI₂-mimetic, a thromboxane (TXA₂) inhibitor, a compound possessing TXA₂-agonistic and TXA₂-inhibiting properties, a compound possessing TXA₂-antagonistic and PGI₂-mimetic activities, and a TXA₂-antagonist which amounts being effective to ameliorate the symptoms thereof].

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